

**REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

In the specification, paragraph number 119 has been amended on page 34 to correct a typographical error that Figure 2 rather than Figure 1 shows the Western blot analysis. The description of Figure 2 and Figure 2 support this amendment.

Claims 1-10 are requested to be cancelled. Claims 11-26 are being added.

This amendment adds and deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 11-26 are now pending in this application. These new claims are supported by the original claims and the specification as filed. More specifically, paragraph numbers 034, 056, 070, and 0123-0126.

**Rejection under 35 U.S.C. § 102(b)/103**

**Claims 1-8**

Claims 1-8 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Kim *et al.* ("Kim"). The Examiner alleges that Kim teaches treatment of hemophilia B by administering 25 U/kg monoclonal antibody purified factor IX, which the Examiner states possesses a specific activity between 5 and 200% of the specific activity of human Factor IX isolated from plasma. The Examiner further states that while the claims require that the Factor IX be from a transgenic non-human mammal, there are no characteristics of the Factor IX of the claimed method that distinguish it from the Factor IX of Kim. Based on this statement, the Examiner alleges that Kim either anticipates or renders obvious the claimed method of treating hemophilia B. Further, at the time of the present invention, the Examiner alleges that it would be obvious to the ordinary

skilled person to treat hemophilia B by the claimed method in view of Kim which allegedly teach a method of using Factor IX having the same properties.

Applicants respectfully traverse this rejection and submit that the claimed Factor IX that is expressed in a transgenic pig possesses different properties, and therefore, the claimed Factor IX is different than the Factor IX of Kim, and further is not obvious over the Factor IX of Kim. In support of this statement, applicants herewith provide as Exhibit 1, a declaration by one of the inventors, Dr. William H. Velander, which provides evidence of the differences between the Factor IX of Kim (“Mononine®”) and the claimed transgenic Factor IX (“TG-FIX”). Particularly, paragraph 4 of this declaration disclose that Mononine® had a higher post-infusion recovery of activity and antigen, but a faster decay than TG FIX. Additionally, Figure 1, discussed in paragraph 5 of Dr. Velander’s declaration, shows that the half-life of TG FIX is approximately 27 hours in circulation whereas the half-life of Mononine® is approximately 17 hours. Further the mean residence time (MRT) of TG FIX is approximately 40 hours whereas the MRT of Mononine® is approximately 20 hours. From this data, Dr. Velander concludes that the claimed TG FIX possesses a different *in vivo* recovery, half-life and MRT as compared to Mononine®. Thus, applicants believe that this data is sufficient to support applicants’ position that Mononine® is different from the claimed TG FIX, and therefore, the claimed method of treatment with TG FIX is not anticipated by Kim. In the same vein, Kim’s disclosure does not render the claimed method of treatment obvious as Mononine® and the TG FIX used in the claimed method possess different properties. In view of this evidence, applicants request the withdrawal of this rejection

#### Claims 9 and 10

Claims 9 and 10 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Kim *et al.* (“Kim”). The Examiner applies Kim as set forth above in the rejection of claims 1-8, and alleges that it would have been obvious to the skilled person to make the claims TG FIX in view of Kim’s Mononine® which allegedly has the same properties. The Examiner bases this rejection on her opinion that Kim allegedly discloses an identical product or only a slightly different product. For the same reasons that are based on the evidence provided in Dr. Velander’s declaration,

applicants traverse this rejection and submit that they have provided data that supports their position that the claimed TG FIX that is produced in a transgenic pig is different than Kim's Mononine®, and therefore, is not anticipated or rendered obvious by Kim's disclosure. In view of the foregoing, it is requested that this rejection be withdrawn.

### CONCLUSION

Applicant believes that the present application containing pending claims 11-26 is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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